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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	9

DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,091	KILLARY ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-100* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1–100 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, 24-33, 44, and 97-100, drawn to an isolated polynucleotide encoding an amino acid sequence of SEQ ID NO: 1, an isolated polynucleotide having a nucleic acid sequence of SEQ ID NO: 3, classifiable in class 536, subclass 23.1.

II. Claim 1, 24-33, and 44, drawn to an isolated polynucleotide encoding an amino acid sequence of SEQ ID NO: 2, classifiable in class 536, subclass 23.1.

III. Claims 18-23, drawn to a peptide comprising about several contiguous amino acid of SEQ ID NO: 1, classifiable in class 530, subclass 300 and subclass 350.

IV. Claims 18-23, drawn to a peptide comprising about several contiguous amino acid of SEQ ID NO: 2, classifiable in class 530, subclass 300 and subclass 350.

V. Claims 34-43, 69-74, and 78-80, drawn to a method for suppressing tumor growth of a cancer cell comprising contacting said cells with an expression cassette comprising a polynucleotide encoding a polypeptide having the sequence of SEQ ID NO: 1, classifiable in class 514, subclass 44.

VI. Claims 34-43, 69-74, and 78-80, drawn to a method for suppressing tumor growth of a cancer cell comprising contacting said cells with an expression cassette comprising a polynucleotide encoding a polypeptide having the sequence of SEQ ID NO: 2, classifiable in class 514, subclass 44.

VII. Claims 45-49, drawn to a monoclonal antibody that binds immunologically to a peptide having the sequence of SEQ ID NO: 1, classifiable in class 530, subclass 387.1.

VIII. Claims 45-49, drawn to a monoclonal antibody that binds immunologically to a peptide having the sequence of SEQ ID NO: 2, classifiable in class 530, subclass 387.1.

IX. Claim 50-55, 58, 59, and 61, drawn to a method of diagnosing a cancer using an antibody that binds to a CAR-1 polypeptide, classifiable in class 435, subclass 7.1.

X. Claim 50-57 and 60-64, drawn to a method of diagnosing a cancer comprising assessing the level of CAR-1 expression, classifiable in class 435, subclass 6.

XI. Claims 65-68 and 75-77, drawn to a method for altering the phenotype of a tumor cell comprising administering to a cell a tumor suppressor designated CAR-1, classifiable in class 514, subclass 2.

XII. Claims 81 and 82, drawn to a non-human transgenic eukaryote lacking a functional CAR-1 gene, classifiable in class 800, subclass 8.

XIII. Claims 83 and 84, drawn to a non-human transgenic eukaryote that over-expresses CAR-1, classifiable in class 800, subclass 8.

XIV. Claims 85-96, drawn to a method for screening a candidate substance for anti-tumor activity, classifiable in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The polynucleotide sequence in Invention I and the polynucleotide in invention II, the peptide in invention III, the peptide in invention IV, the monoclonal antibody in invention VII, the monoclonal antibody in invention VIII, the non-human transgenic eukaryote in invention XII, and the non-human transgenic eukaryote in invention XIII are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are directed to distinct inventions that are not disclosed as capable of use together and each invention has a different mode of operation, different function and different effect. Additionally, polynucleotides, peptides, and antibodies can be used by materially different methods. Polynucleotides can be used as detection probes, polypeptides can be used for antigen presenting cell priming and antibodies can be used in screening assays, for example. The differences between Invention I and Inventions II, III, IV, VII, VIII, XII, and XIII are further underscored by their divergent classification and independent search status.

Invention V and inventions VI, IX, X, XI and XIV are patentably distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are directed to distinct methods. The therapeutic method in invention V is not disclosed as capable of use together with inventions VI, IX, X, XI, and XIV. In addition, the method in invention V has a different mode of operation, different function and different effect than the methods in inventions VI, IX, X, XI and XIV. The

differences between Invention V and inventions VI, IX, X, XI, and XIV are further underscored by their divergent classification and independent search status.

Invention I and inventions V, X, and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method in inventions V, X, and XIV can use materially different products, e.g., a polynucleotide encoding SEQ ID NO: 1 or a polynucleotide encoding SEQ ID NO: 2.

Invention II and inventions VI, X, and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method in inventions VI, X, and XIV can use materially different products, e.g., a polynucleotide encoding SEQ ID NO: 1 or a polynucleotide encoding SEQ ID NO: 2.

Invention III and Inventions XI and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in two materially different methods, e.g., Invention XI or XIV. In addition, the method in invention XI or

invention XIV can use a materially different product, e.g., peptide comprising amino acid of SEQ ID NO: 2.

Invention IV and Inventions XI and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in two materially different methods, e.g., Invention XI or XIV. In addition, the method in invention XI or invention XIV can use a materially different product, e.g., peptide comprising amino acid of SEQ ID NO: 1.

Invention VII and invention IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method in invention IX can use materially different products, e.g., a monoclonal antibody that binds an immunologically to a peptide having the sequence of SEQ ID NO: 2, or a polyclonal antibody that binds an immunologically to a peptide having the sequence of SEQ ID NO: 2.

Invention VIII and invention IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case, the method in invention IX can use materially different products, e.g., a monoclonal antibody that binds an immunologically to a peptide having the sequence of SEQ ID NO: 1, or a polyclonal antibody that binds an immunologically to a peptide having the sequence of SEQ ID NO: 1.

Claim 50 link(s) inventions IX and X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 50. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and the search required for any Group listed is not required for any other Group and a search of the groups would not be co-extensive, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman, 1635

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER